UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

TAMMY ALLEN, PERSONAL REPRESENTATIVE OF THE ESTATE OF NORMAN ALLEN, Plaintiff,	)	**1:05-CV-011463**
V.	)	
THE UNITED STATES OF AMERICA, Defendant.	)	

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PLAINTIFF'S TRIAL MEMORANDUM

DESCRIPTION OF THE CASE:

This is a medical malpractice action brought by the plaintiff, Tammy Allen, Personal Representative of the Estate of Norman Allen. The plaintiff seeks recovery on behalf of Norman Allen's wife, Ruth Allen, and her children, Stephen Allen and Tammy Allen, for the conscious pain and suffering and wrongful death of Norman Allen, as a result of the negligent, inadequate, and unacceptable medical care and treatment rendered to him by Michael Kelly, M.D., a servant, agent or employee of the defendant, The United States of America.

Norman Allen died of metastatic rectal cancer on May 18, 2002. His cancer was not detected until it had already spread to his lymph nodes. Had Norman Allen received regular colorectal screening from Michael Kelly, M.D., his cancer would have been detected at a stage that is treatable and amenable to cure. The plaintiff, Tammy Allen, alleges damages on behalf of the estate of Norman Allen for his conscious pain and suffering. The plaintiff also alleges damages on behalf of Norman Allen's wife, Ruth Allen, and his children, Stephen Allen and Tammy Allen, for their respective losses of their relationships with Norman Allen.

The plaintiff expects that the evidence will demonstrate that as a direct result of the failure of the defendant, The United States of America, by and through its agent, servant, and employee, Michael Kelly, M.D., to adhere to the accepted standard of care, Norman Allen did not receive colorectal cancer screening. Colorectal screening consists of a digital rectal exam, fecal occult blood testing, barium enema with sigmoidoscopy, or colonoscopy.

The plaintiff expects that the evidence will show that Michael Kelly, M.D. failed to adhere to the accepted standard of care at the time for the average qualified physician when he failed to order or offer to perform colorectal cancer screening for Norman Allen based on his age, and positive family history for rectal cancer. Dr. Kelly further failed to adhere to the accepted standards of care when he failed to perform testing to diagnose colorectal cancer screening on Norman Allen in 1999, despite Mr. Allen's reports of pain, weight loss, frequent bowel movements, and bloody stool.

The evidence will further show that had Michael Kelly, M.D. performed colorectal cancer screening on Norman Allen in accordance with the accepted standard of care, Mr. Allen's rectal cancer would have been detected before it spread to his lymph nodes. Had Dr. Kelly rendered care in accordance with the accepted standard, with reasonable medical certainty, Norman Allen would not have suffered conscious pain and suffering and a wrongful death.

The delayed detection of Mr. Allen's rectal cancer is a direct result of Dr. Kelly's failure to perform timely colorectal cancer screening. When detected early, rectal cancer is very treatable and amenable to cure. If detected after it has spread beyond the rectum to the lymph nodes, a rectal cancer patient is likely to die from the disease. Early detection and diagnosis is considered essential to halting the progression of rectal cancer. Colorectal cancer screening in the form of a digital rectal examination, fecal occult blood testing, barium enema with

sigmoidoscopy, or colonoscopy, is essential to early detection. Risk factors for developing rectal cancer include family history and being over the age of 50. As an individual over the age of 50 with a family history of rectal cancer, Norman Allen was at risk for developing rectal cancer and should have received colorectal cancer screening from Dr. Kelly. Had Norman Allen received colorectal cancer screening from Dr. Kelly, more likely than not his rectal cancer would have been diagnosed at a curable stage, and he would not have sustained conscious pain and suffering and a wrongful death.

The plaintiff also expects that the evidence will show that the defendant, The United States of America, is a public employer within the meaning of 28 U.S.C. §§1346(b) and 2671 et seq. and at all times herein relevant operated and/or funded Greater Lawrence Family Health Center in Lawrence, Massachusetts, where Dr. Kelly was an employee when he rendered his substandard care to Norman Allen.

FACTUAL BACKGROUND:

Norman Allen was a patient of Michael Kelly, M.D., from 1997 until September 1999. When he first saw Dr. Kelly in 1997, Mr. Allen was 50 years old. Mr. Allen's medical history was significant for positive rectal cancer in his father. Mr. Allen's past medical history also included a seizure disorder, chronic back and neck pain, a remote history of a benign lung tumor, and question of fibromyalgia. As an adult over the age of 50 with family history of rectal cancer in his father, Mr. Allen was at increased risk of developing rectal cancer.

During the time period that Mr. Allen was under the care of Dr. Kelly, colorectal cancer screening was never performed or offered to Mr. Allen by Dr. Kelly despite the fact that Mr. Allen was over 50 years of age. At all relevant times, colorectal cancer screening consisted of a digital rectal examination, sigmoidoscopy with barium enema, fecal occult blood testing, or a colonoscopy. A digital rectal examination is a standard part of an annual physical examination for an adult male. Dr. Kelly testified at his deposition that he understood the standard of care required colorectal cancer screening, Dr. Kelly admitted that he failed to offer or perform colorectal cancer screening because he was "distracted".

On April 6, 1999, at the age of 51 ½ years, Mr. Allen told Dr. Kelly that he was experiencing frequent bowel movements and weight loss. Weight loss and a change in bowel pattern are symptoms associated with colorectal cancers. However, according to the medical records, Dr. Kelly neither offered nor performed a sigmoidoscopy or colonoscopy to determine the cause of Mr. Allen's change in bowel pattern and weight loss. Furthermore, Dr. Kelly neither offered nor performed any testing for colorectal cancer in the form of a digital rectal exam, fecal occult blood testing, sigmoidoscopy with barium enema or colonoscopy in a symptomatic patient over 50 years of age.

On July 13, 1999, Mr. Allen followed up with Robert Simms, M.D. for evaluation of his fibromyalgia. Mr. Allen reported to Dr. Simms that he had been experiencing intermittent episodes of bloody stool. Dr. Simms encouraged Mr. Allen to follow-up with Dr. Kelly. Dr. Simms also sent Dr. Kelly a copy of his dictated report that contained reference to Mr. Allen's episodes of bloody stool. As recommended, Mr. Allen followed up with Dr. Kelly on August 3, 1999, but Dr. Kelly made no reference to Mr. Allen's episodes of bloody stool. Dr. Kelly noted that he was aware of Mr. Allen's visit with Dr. Simms, but deferred a physical examination of Mr. Allen. Dr. Kelly neither offered nor performed any testing for colorectal cancer in the form of a rectal exam, fecal occult blood testing, sigmoidoscopy with barium enema, or colonoscopy in a symptomatic patient over 50 years of age.

In September of 1999, Mr. Allen switched his healthcare provider to David Farzan, M.D. On September 27, 1999, Mr. Allen presented to Dr. Farzan for a physical exam. Dr. Farzan noted Mr. Allen's history of hematochezia (bloody stool) and his family history of rectal cancer. A rectal exam revealed no masses and the hemoccult was negative. Dr. Farzan referred Mr. Allen to Thomas Fazio, M.D., a gastroenterologist, for an evaluation.

On October 4, 1999, Mr. Allen presented to Dr. Fazio with complaints of rectal bleeding, frequent bowel movements, a feeling of incomplete bowel movements, alternating diarrhea and constipation, and lower abdominal cramps. Dr. Fazio noted Mr. Allen's family history of rectal cancer and ordered a colonoscopy.

Norman Allen underwent a colonoscopy on October 20, 1999, which showed a 3cm mass located at 6cm in the rectum. The mass was biopsied and pathology showed

moderately differentiated adenocarcinoma of the rectum. A transrectal ultrasound performed on November 3, 1999 showed evidence of invasion and involvement of the muscularis propria. Mr. Allen underwent a surgical low anterior resection for his rectal cancer on December 1, 1999. Pathology from the surgical specimen showed lymphatic invasion with one of six lymph nodes positive for metastatic adenocarcinoma that extended beyond the lymph node capsule. Mr. Allen was diagnosed with Stage III rectal cancer.

Postoperatively, Mr. Allen received chemotherapy and radiation. Mr. Allen remained in stable condition until April 2002 when extensive liver metastasis was found. On May 18, 2002, at the age of 54, Mr. Allen died from metastatic rectal cancer. At the time of his death, he had a life expectancy of 24.9 more years, and a work-life expectancy of 11 more years.

LIABILITY OF THE DEFENDANT:

The plaintiff is proceeding on two separate legal theories. The first is negligence. The second is informed consent.

Negligence

The plaintiff alleges and intends to prove that the defendant, through Michael Kelly, M.D., was negligent when Dr. Kelly failed to offer or perform colorectal cancer screening on Norman Allen between 1997 and 1999. Dr. Kelly knew, or should have known, that Mr. Allen was at risk for developing rectal cancer. These risks include being over 50 years of age and positive family history of rectal cancer in his father. Despite these risk factors, Dr. Kelly failed to order or offer to perform colorectal cancer screening on Norman Allen.

The plaintiff claims that, to a reasonable degree of medical certainty, the care and treatment rendered to Norman Allen by Dr. Kelly from 1997 to 1999 fell below the accepted standard of care for the average qualified internal medicine physician when Dr. Kelly failed to perform or offer to perform colorectal screening on Norman Allen. As a direct result of Dr. Kelly's deviation from the accepted standard of care, the diagnosis and subsequent treatment of Mr. Allen's rectal cancer was significantly delayed, allowing it to grow and spread beyond his rectum to his lymph nodes. Had Dr. Kelly complied with the accepted standard of care, he would have performed testing for colorectal cancer, including digital rectal exam, sigmoidoscopy with barium enema or a colonoscopy to completely visualize Mr. Allen's colon and rectum, he would have detected a cancerous lesion earlier than October 1999, and, more likely than not, Mr. Allen would not have sustained conscious pain and suffering and a premature death from metastatic rectal cancer on May 18, 2002.

Informed Consent

It is well settled under Massachusetts law that a patient has a right to be informed of his condition and the available treatment options. The decision to undergo a course of treatment belongs to the patient, not to the doctor. In order to make an informed decision, the patient must be provided with all of the relevant information, and must be permitted to make an informed decision after considering the risks and benefits of each available procedure or course of treatment.

Dr. Kelly's failure to disclose to Norman Allen the risks and benefits of colorectal cancer screening in the form of a digital rectal exam, fecal occult blood testing, sigmoidoscopy with barium enema or colonoscopy constitutes a breach of Dr. Kelly's duty to obtain Norman Allen's informed consent. The evidence will be that Norman Allen was at risk of developing rectal cancer and that Dr. Kelly never considered or disclosed to Norman Allen the risk for developing rectal cancer, the nature and probability of risks involved with not conducting colorectal cancer screening, the benefits to be reasonably expected from available alternative treatment, and the risks to be reasonably expected from the available alternative treatment. The evidence will also show that had Norman Allen been presented with the opportunity of receiving colorectal cancer screening, that Mr. Allen, and a reasonable person in Mr. Allen's situation, would have chosen to receive colorectal cancer screening, given the risks and benefits of screening, as compared to Mr. Allen's risk of developing rectal cancer.

EXPECTED EVIDENTIARY ISSUES:

No unusual evidentiary issues are anticipated at this time.

LIST OF WITNESSES:

1. Tammy Allen (plaintiff and daughter of Norman Allen)
   876 Laconia Road
   Tilton, NH 03276

2. Ruth Allen (wife of Norman Allen)
   818 Ohio Street, Apt. 20
   Bangor, ME 04401

3. Stephen Allen (son of Norman Allen)
   Bangor, ME

4. Michael Kelly, M.D. (defendant)
   32 Old Middle Street
   Goshen, CT

5. Alfred I. Neugut, M.D. (expert witness, affidavit previously submitted)
   Division of Medical Oncology
   Department of Medicine
   New York Presbyterian Hospital
   722 West 168th Street
   New York, NY 10032

DEPOSITIONS TO BE USED AT TRIAL:

The plaintiff does not intend to use any depositions at trial as part of her case, other than possibly for impeachment in cross-examination.

EXHIBITS TO BE INTRODUCED WITHOUT OBJECTION:

The plaintiff anticipates introducing the following exhibits at trial:

1. Medical Records from Holy Family Hospital
2. Medical Records from Lawrence General Hospital
3. Medical Records from Northeast Urologic Surgery, P.C.
4. Medical Records from Greater Lawrence Family Health Center: Michael Kelly, M.D.
5. Medical Records from Pentucket Medical Associates
6. Medical Records from Andover Surgical Associates
7. Medical Records from Greater Lawrence Family Health Center: Thomas Fazio M.D. and David Farzan, M.D.
8. Medical Records from Howard P. Taylor, M.D.
9. Medical Records from Boston University Medical Center
10. Medical Records from Merrimack Imaging
11. Medical Records from Seacoast Hospice
12. Curriculum Vitae of Alfred I. Neugut, M.D.
13. Certificate of Appointment from The State of New Hampshire, Rockingham Probate Court, Kingston, New Hampshire, confirming Tammy Allen's appointment to administer the estate of Norman G. Allen.
14. Massachusetts Allowance of Foreign Will, issued by The Trial Court of the Commonwealth of Massachusetts, Probate and Family Court Department.

15. Brendler, Sarah J., M.D. and Tolle, Susan, W., M.D., "Fecal Occult Blood Screening and Evaluation for a Positive Test", **Western Journal of Medicine**, Volume 146, No. 1, pp. 103-105 (January 1987).

16. Eddy, David M., M.D., Ph.D., "Screening for Colorectal Cancer", **Annals of Internal Medicine**, Volume 113, No. 5, pp. 373-384 (September 1, 1990).

17. Ahlquist, David A., M.D., Klee, George, G., M.D., Ph.D., McGill, Douglas B., M.D. and Ellefson, Ralph D., M.D., "Colorectal Cancer Detection in the Practice Setting, Impact of Fecal Blood Testing", **Archives of Internal Medicine**, Volume 150, No. 5 pp. 1041-1045 (May 1990).

18. Eisner, Mark S., M.D. and Lewis, James H., M.D., "Diagnostic Yield of a Positive Fecal Occult Blood Test Found on Digital Rectal Examination", **Archives of Internal Medicine**, Volume 151, No. 11 pp. 2180-2184 (November 1991).

19. Brint, Steven L., M.D., DiPalma, Jack A., M.D., and Herrera, Jorge L., M.D., "Is a Hemoccult-Positive Rectal Examination Clinically Significant?", **Southern Medical Journal**, Volume 86, No. 6 pp. 601-603 (June 1993).

20. Gelfand, David W., M.D., "Colorectal Cancer, Screening Strategies", **Radiologic Clinics of North America**, Volume 35, No. 2 pp 431-438 (March 1997).

21. Early, Dayna S., M.D., "Colorectal Cancer Screening: An Overview of Available Methods and Current Recommendations.", Volume 92, No. 2 pp. 258-265 (March 1999).

22. Winawer, Sydney J., M.D., Zauber, Ann G., Ph.D., Ho, May Nah, M.S., O'Brien, Michael J., M.D., Gottlieb, Leonard S., M.D., Sternberg, Stephen S., M.D., Waye, Jerome D., M.D., Schapiro, Melvin, M.D., Bond, John H., M.D., Panish, Joel, F., M.D., Ackroyd, Frederick, M.D., Shike, Moshe, M.D., Kurtz, Robert C., M.D., Hornsby – Lewis, Lynn, M.D., Gerdes, Hans, M.D., Stewart, Edward T., M.D., and the National Polyp Study Workgroup, "Prevention of Colorectal Cancer by Colonoscopic Polypectomy", **The New England Journal of Medicine**, Volume 329, No. 27 pp. 1977-1981 (December 1993).

23. Selby, Joe V., M.D., M.P.H., Friedman, Gary D., M.D., M.S., Queensberry Jr., Charles P., Ph.D.., and Weiss, Noel, M.D., Dr.p.H., "A Case-Control Study of Screening Sigmoidoscopy and Mortality from Colorectal Cancer", **The New England Journal of Medicine**, Volume 326, No. 10 pp. 654-657 (March 1992).

24. Newcomb, Polly A., Norfleet, Robert G., Storer, Barry E., Surawicz, Tanya S., Marcus, Pam M., "Screening Sigmoidoscopy and Colorectal Cancer Mortality", **Journal of the National Cancer Institute**, Volume 84, No. 20 pp. 1572-1575 (October 1992).

25. Winawer, Sidney J., M.D., Flehinger, Betty J., M.D., Schottenfeld, David, M.D., Miller, Daniel G., M.D., "Screening for Colorectal Cancer with Fecal Occult Blood Testing and Sigmoidoscopy", **Journal of the National Cancer Institute**, Volume 85, No. 16 pp. 1311-1318 (August 1993).

26. Winawer, Sidney J.; Fletcher, Robert H.; Miller, Laura; Godlee, Fiona; Stolar, Michael H.; Mulrow, Cynthia D.; Woolf, Steven H.; Glick, Seth N.; Ganiats, Theodore G.; Bond, John H.; Rosen, Lester; Zapka, Jane G.; Olsen, Sharon J.; Giardiello, Francis, M.; Sisk, Jane E.; Antwerp, Ross Van; Brown-Davis, Carolyn; Marciniak, Debra A; Mayer, Robert J., "Colorectal Cancer Screening: Clinical Guidelines and Rationale," **Gastroenterology, American Gastroenterological Association,** Volume 112, No. 2 pp. 594-642 (1997).

MARKED ITEMS TO BE OFFERED AT TRIAL TO WHICH THE DEFENDANT HAS RESERVED THE RIGHT TO OBJECT:

The plaintiff does not have any marked items to which the defendant has reserved the right to object. The plaintiff does not intend to offer any marked items at trial, apart from the exhibits to be introduced with out objection.

NOTICE OF PLAINTIFF'S INTENT TO CROSS EXAMINE:

The plaintiff has given notice of her intent to cross-examine the defendant's expert witnesses, Dr. David Patrick Ryan, Dr. James A. Talcott, and Dr. James Richter. The plaintiff also reserves the right to cross-examine any additional expert or non-expert witnesses that the defendant may call.

FINDINGS OF FACT AND RULINGS OF LAW:

The plaintiff attaches as a separate document her proposed Findings of Fact and Rulings of Law.

Respectfully submitted,
The plaintiff,
By her attorney,

/s/ William J. Thompson
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